

## URGENT FIELD SAFETY NOTICE

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**Commercial Name of the Affected Product: Durex Real Feel, Durex Latex Free**

**FSCA-identifier: RB-88977-2018**

**Type of Action: Consumer Recall of Medical Device**

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Date: 30<sup>th</sup> July 2018

**Attention: CONSUMER RECALL OF AFFECTED BATCHES OF DUREX REAL FEEL & DUREX LATEX FREE**

This relates to the Durex Real Feel 'Latex-free' and Durex Latex Free Polyisoprene condoms.



### Description of the Problem:

The safety of our consumers always comes first, and this is reflected in our rigorous quality standards. We recently found that a limited number of the above condoms made earlier this year are not passing our stringent shelf-life durability tests.

Our tests have shown that some batches which are currently on the market in UK & Ireland (and in other markets) do not pass the requirements for burst pressure towards the end of the shelf life for the product. The expiry date of the affected batches is between Dec. 2020 and Feb. 2021.

Only for the batches of condoms affected by this issue, there could be an increase in the number of condoms that burst during application or use. Always read the label which states "Should a condom leak or burst during use, seek doctor or pharmacist assistance as soon as possible, at least within 72 hrs."

Our condoms are intended to provide a method of contraception and prevent the transmission of sexually transmitted infections (STIs) through a non-latex barrier that offers a benefit to consumers sensitive to latex.

There is no immediate safety concern for consumers and only a limited number of batches are affected. We are working with relevant competent authorities in all affected markets regarding relevant recall actions.

**RB UK Commercial Ltd and Reckitt Benckiser Ireland**

**Advice on Action to be Taken by User:**

**Consumers**

We ask consumers to return non-latex Durex Real Feel and Durex Latex Free condoms with the following batch numbers to the store they bought them from for a full refund:

Description	SKU Code	Batch Number	Expiry Date
Durex Latex Free 12 Pack	3014272	1000444367	Feb-2021
		1000433145	Jan-2021
Durex Real Feel 6 Pack	3040039	1000438054	Jan-2021
Durex Real Feel 12 Pack	3014278	1000444370	Feb-2021
	3014277	1000419930	Jan-2021
		1000444367	Feb-2021
		1000416206	Dec-2020
Durex Real Feel 18 Pack	3030444	1000434066	Jan-2021
		1000430479	Jan-2021
Durex Real Feel 18 Pack (RF Tag)	3030445	1000430479	Jan-2021

Consumers who have purchased one of the affected batches via an online retailer will be contacted by email via their online retailer.

You will find the batch number on the bottom of the pack and on the foil wrapping of individual condoms. Please see the example below:



More information on returns can be found on the Durex website: [www.durex.co.uk](http://www.durex.co.uk) and [www.durex.ie](http://www.durex.ie). If consumers have any questions, we encourage them to call the Durex care line on 0333 2005 345 for the UK or (01) 630 5429 for ROI or contact us via e-mail [consumer.relations-hcukroi@rb.com](mailto:consumer.relations-hcukroi@rb.com).

**Wholesalers and Trade Partners**

**RB UK Commercial Ltd and Reckitt Benckiser Ireland**

Registered Office: Reckitt Benckiser Group Plc. 103-105 Bath Road. Slough.UK. SL1 3UH

Wholesalers and Trade Partners should quarantine all affected stocks with immediate effect and contact all distribution points to inform them of the recall action. All affected product should be immediately removed from store shelves. RB will contact wholesalers and trade partners to advise the distributed quantities and to organise collection of all stock.

### **Pharmacists**

All affected product should be immediately removed from store shelves. Pharmacies should return all stock to their wholesaler. RB will contact wholesalers to organise collection of all stock.

### **NHS (UK only)**

There had been no distribution of these products to the NHS.

### **Transmission of this Field Safety Notice:**

Wholesalers and Trade Partners: Please forward to the relevant distribution points in your supply chain who have received the affected products.

RB wishes to apologise for the inconvenience caused and thanks you for your cooperation with this matter.

### **Reckitt Benckiser Healthcare (UK) Ltd QPPV:**

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